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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,808	11/03/2003	Jamie Crawford	5434-4	4460

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EXAMINER	
GILBERT, ANDREW M	
ART UNIT	**PAPER NUMBER**
3767	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

HH

Office Action Summary	Application No.	Applicant(s)	
	10/699,808	CRAWFORD ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6 and 8-33* is/are pending in the application.

4a) Of the above claim(s) *12,13 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,8-11,14-18 and 20-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/13/2007 has been entered.

Acknowledgements

2. This office action is in response to the reply filed on 2/13/2007.

3. In the reply, the applicant amended independent claims 1, 2, 6, 8, 9, 20, 26; added new claims 29-33; and cancelled claims 5 and 7. Claims 12, 13, and 19 remain withdrawn. Thus, claims 1-4, 6-11, 14-18, 20-33 are pending.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 6, 8-11, 14-18, 20-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Guerineau et al (5267976). In reference to independent claims 1, 20, 26 Guerineau et al discloses discloses a medical device having a syringe assembly having a barrel (1) having a forward end and a rear end and defining a reservoir within which

the medicament may be contained, said barrel having a radial flange (24) arranged between said forward end and said rear end; a needle cannula (6) having a forward tip and being coupled to said forward end of said barrel and in fluid communication with said reservoir; a plunger (11) having a first end with a stopper positioned in said reservoir and a second end having a thumb pad (12, 22) for receiving medicament delivery pressure for causing said plunger to move within said reservoir to cause the medicament to be expelled from said reservoir (Fig 1-3); a hollow shield body (14) receiving said syringe barrel therein, said syringe barrel being selectively movable within said shield body between a first position in which said forward tip of said needle cannula is exposed, and a second position in which said forward tip of said needle cannula is contained within said shield body (Fig 1, 3); a first retainer (19) fixedly coupled to said hollow shield (Fig 1) to prevent axial movement of said first retainer with respect to said hollow shield body, said first retainer releasably securing said syringe barrel in said first position and a second retainer (20) spaced axially from said first retainer, wherein said radial flange is position between said first and second retainers when said syringe barrel is in said second position (19, 24, 20, Fig 3); and an urging member (17) acting on a portion of said hollow shield body and said radial flange of said syringe barrel for urging said syringe barrel from said first position toward said second position (Fig 1, 3), said thumb pad being configured to interact with said first retainer upon movement of said stopper to a position proximate said syringe barrel forward end to release said syringe barrel from said first retainer and enable said urging member to

move said syringe barrel from said first position to said second position upon release of medicament delivery pressure from said thumb pad (Fig 1, 3; col 3, lns 39-56).

6. In reference to independent claim 29 Guerineau et al discloses a medical device for delivering a medicament to a patient, comprising: a reservoir (1) within which the medicament may be contained and having a unitarily molded feature (24), said reservoir having a forward end to which a needle cannula (6) may be connected; a plunger (11) receivable in said reservoir and having a thumb pad (12, 22); a hollow shield body (14) coupled with said reservoir, said reservoir being selectively movable with respect to said shield body between a first position in which a forward tip of the needle cannula is exposed (Fig 1), and a second position in which a forward tip of the needle cannula is contained within said hollow shield body (Fig 3), said hollow shield body having a first retainer (19) for engaging said reservoir to releasably secure said hollow shield body in said first position, and having a second retainer (20) for directly engaging said unitarily molded feature of said reservoir to secure said hollow shield body in said second position; and said thumb pad being configured to interact with said first retainer upon movement of said plunger in a direction toward said forward end of said reservoir to release said first retainer and enable movement of said reservoir from said first position to said second position (Fig 1, 3; col 3, lns 39-56).

7. In reference to claims 2-4, 6, 21-24, Guerineau et al discloses wherein said the is fully capable of having a hollow shield body (Figs 7-9) further comprises a flange clip (40) connected proximate a rear facing end (41) of said hollow shield body, wherein said flange clip comprises said first and second retainers (19', 20'; wherein the

Examiner notes that the retainers 19', 20' are fully capable of engaging the radial flange 24 (see col 5, lns 44-46, 62-67); wherein said hollow shield body further comprises a rim (41) and said flange clip comprises a recess engaging said rim for connecting said flange clip to said hollow shield body (Figs 7-9, col 5, lns 32-38); wherein said hollow shield body further comprises a step (15) having a rear facing surface for receiving an end of said urging member (15, 17, Figs 1-3); wherein said step divides said hollow shield body into a first cylindrical portion (15) having a first diameter and a second cylindrical portion (14) having a second diameter different than said first diameter, said urging member being arranged in said second cylindrical portion (17, 14, Fig 1).

8. In reference to claims 8 (see 19, 20, 24, Figs 1-3, and col 3, lns 39-56); claim 9 (see 19, 20); claim 10 (see 17); claim 11 (see 19, 20; Figs 1-3, and col 3, lns 39-56); claim 14 (see Fig 1-3; wherein the Examiner notes it is well known in the art to make syringes from plastic material); claim 15 (see 15; Fig 1); claim 16 (see 16, Fig 1); claim 17 (see 3, 4, Fig 1), claim 18 (see 19, 24, 20; Figs 1-3, and col 3, lns 39-56); claim 25, (see 17), claim 27 (see 12, 22); claim 28 (see 17); claim 30 (see 19, 24, 20; Figs 1-3, and col 3, lns 39-56), claim 31 (see 19, 20); claim 32 (see Fig 1-3; wherein the Examiner notes it is well known in the art to make syringes from plastic material); claim 33 (see 19, 24, 20; Figs 1-3, col 39-56).

9. (***)

10.

11. Claims 1-6, 10, 14, 15-18, 20-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonnet (6206853). In reference to claims 1, 20, 26-27, Bonnet discloses a medical device having a syringe assembly having a barrel (1) having a forward end and a rear end and defining a reservoir within which the medicament may be contained (Fig 1); a needle cannula (3) having a forward tip and being coupled to said forward end of said barrel and in fluid communication with said reservoir (Fig 1); a plunger (4) having a first end with a stopper positioned in said reservoir and a second end having a thumb pad (Fig 1) for receiving medicament delivery pressure for causing said plunger to move within said reservoir to cause the medicament to be expelled from said reservoir (Fig 1-3); a hollow shield body (5) receiving said syringe barrel therein, said syringe barrel being selectively movable within said shield body between a first position in which said forward tip of said needle cannula is exposed, and a second position in which said forward tip of said needle cannula is contained within said shield body (Figs 1-3); a first retainer (11, 7) fixedly coupled to said hollow shield (Figs 1-3) to prevent axial movement of said first retainer with respect to said hollow shield body, said first retainer releasably securing said syringe barrel in said first position; and an urging member (6) arranged between a portion of said hollow shield body and a portion of said syringe barrel for urging said syringe barrel from said first position toward said second position (Figs 1-3), said thumb pad being configured to interact with said first retainer upon

movement of said stopper to a position proximate said syringe barrel forward end to release said syringe barrel from said first retainer and enable said urging member to move said syringe barrel from said first position to said second position upon release of medicament delivery pressure from said thumb pad (Figs 1-3).

12. In reference to claims 2-6, 15-17, 21-24, Bonnet additionally discloses a hollow shield body further comprises a flange clip (11) connected proximate a rear facing end of said hollow shield body, wherein said flange clip comprises said first retainer (Fig 1, 8); the hollow shield body further comprises a rim (Fig 6) and said flange clip comprises a recess (Fig 9) engaging said rim for connecting said flange clip to said hollow shield body (Fig 1); the hollow shield body further comprises a step (Fig 1) having a rear facing surface for receiving an end of said urging member (6); the syringe barrel further comprises a radial flange (2, Fig 1) for receiving another end of said urging member (6, Fig 1); the step divides said hollow shield body into a first cylindrical portion having a first diameter and a second cylindrical portion having a second diameter different than said first diameter (Fig 1), said urging member being arranged in said second cylindrical portion (Fig 1); and the flange clip comprises a second retainer (7) spaced axially from said first retainer (Fig 8).

13. In reference to claims 10, 14, 25, 28, Bonnet additionally discloses wherein first and second retainers (7) comprise flexible arms (Figs 1-3, 6-9); wherein the urging member is a spring (6); wherein the syringe barrel is made of plastic (col 6, lns 25-28).

14. In reference to claim 18, Bonnet additionally discloses the first retainer is moved radially outward to release said syringe barrel (Figs 1-3).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claim 7, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonnet in view of Brunel (6186980). Bonnet discloses the invention substantially as claimed except for wherein said radial flange is positioned between said first and second retainers when said syringe barrel is in said second position, wherein a front facing surface of the second retainer and a rear facing surface of the radial flange are mutually inclined to allow said flange to pass over said second retainer when said syringe barrel is moved from said first flange to pass over said second retainer when said syringe barrel is moved from said first position toward second position. Brunel teaches that it is known to have said radial flange is positioned between said first and second retainers when said syringe barrel is in said second position, wherein a front facing surface of the second retainer and a rear facing surface of the radial flange are mutually inclined to allow said flange to pass over said second retainer when said syringe barrel is moved from said first flange to pass over said second retainer when said syringe barrel is moved from said first position toward second position (Figs 12-14, col 8, lns 26-57) for the purpose of securing the syringe barrel in the second position. It would have been obvious to one having ordinary skill in the art at the time the invention

was made to modify the radial flange as taught by Bonnet with the radial flange as taught by Brunel for the purpose of securing the syringe barrel in the second position.

17. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bonnet. Bonnet discloses the invention substantially as claimed except for expressly disclosing wherein the first retainer is formed unitarily with said shield body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the first retainer (11) as taught by Bonnet to be unitarily formed with said shield body (5) since it was well known in the art that it has been held that the term unitarily is sufficiently broad to embrace constructions united by such means as fastening and welding. *In re Hotte*, 177 USPQ 326, 328 (CCPA 1973). In the instant case, the first retainer is fastened and fixedly secured to the shield body.

Response to Arguments

18. Applicant's arguments with respect to claims 1-11, 14-18, 20-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER